TERMS OF REFERENCE FOR THE

"International Cooperation on Cosmetics Regulations" ("ICCR")

AMONG

HEALTH CANADA,
EUROPEAN COMMISSION DG ENTERPRISE AND INDUSTRY,
MINISTRY OF HEALTH, LABOUR, AND WELFARE OF JAPAN,
FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA

SUMMARY MISSION

The purpose of the multilateral framework of the International Cooperation on Cosmetics Regulations ("ICCR") is to maintain the highest level of global consumer protection, while minimizing barriers to international trade.

Working structure of "ICCR"

1. MEMBERSHIP

"ICCR" is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union and Canada.

This group of regulatory authorities defined as the "members" can enter into a constructive dialogue with their relevant cosmetics' industry trade associations.

The ICCR members are: the Food and Drug Administration of the United States of America, the Ministry of Health, Labour, and Welfare of Japan, the European Commission DG Enterprise and Industry, and Health Canada.

The inclusion of other members and their appropriate status can be decided by consensus by the members.

2. Instruments and Implementation

All decisions of the representatives of the members and subsequent actions must be taken by consensus. All decisions to be taken should be compatible with the laws, policies, rules, regulations and directives of the respective administrations and governments and may require the final approval by senior levels of management at a later date in order to allow their operational implementation or transposition into practice.

Representatives of the members agree to take appropriate steps to implement the items that have reached consensus within the boundaries of their legal and institutional constraints. In this respect they agree to promote the documents reflecting the consensus within their own jurisdictions and to seek convergence of regulatory policies and practices.

3. DIALOGUE WITH INDUSTRY

While each member holds the ultimate responsibility for implementation, it is recognized that successful implementation requires the input of a constructive dialogue with the cosmetics' industry trade associations and potentially other stakeholders.

It is the responsibility of each of the industry trade associations to ensure they have solicited input from, and adequately represent the vast majority of positions taken by, the affected industry sector. The list of cosmetic industry trade associations is not limited, and can be extended to other relevant associations at the discretion of each member, and when the specific topic warrants the involvement of other interested parties.

4. WORK PROCESS

The ICCR members' representatives normally meet once a year, but may alter the frequency of meetings if considered necessary to ensure progress.

The venue of meetings rotates amongst the territory of the four members.

If required by applicable legal or regulatory policies in each region/country, notice of meetings and draft guidelines to be considered may be publicly notified with adequate time to allow for public comments.

Each member will be allowed up to three representatives. However, each member will have only one vote when deciding by consensus between all members.

The chair of the ICCR meeting is held by a representative of the member hosting the meeting.

The chair is responsible for looking for consensus building among representatives of the members and should have an oversight of all pending and outstanding work.

The chair edits the draft agenda items stemming from the four members and presides over the meeting.

The chair rotates amongst regions/countries each year starting at the end of the previous meeting, and concludes at the adjournment of the meeting held in their region.

4.1. Structure of the meetings

The annual meeting could have the indicated format with three successive sessions, as follows:

First day: Regulator's Caucus, with the agenda items listed by the chair;

<u>Second day</u>: Regulator's + Industry Caucus - structured dialogue between members' representatives and Industry trade associations, and in certain cases, interested parties;

Third day (morning only): Regulator's Caucus, with joint adoption of the meeting's report at the close.

4.2. Responsibilities of the Regulators

The representatives of the members (named here-after the "Regulators") take all decision by consensus.

They provide overall strategic guidance and direction to activities of ICCR;

They define subject areas for ICCR activities and decide on future topics for activity;

They exchange information on regulatory, trade and market developments of interest;

They determine policies related to the ICCR process, administration, and external communications;

They appoint ad-hoc working groups to carry out technical work;

They adopt guidelines and policy statements, including those developed by the adhoc working groups;

They take on any other initiatives that contribute to achieving ICCR objectives.

4.3. Responsibilities of the industry trade associations

The industry trade associations of each region will gather input in order to represent all affected industry sectors on specific issues at meetings with Regulators.

Prior to ICCR meetings, well in advance to allow adequate time for preparation, industry will suggest items for priority actions to be consider by ICCR members.

During the caucus on the second day, Industry will enter in a constructive dialogue with the members and give their opinion and recommendations for future work.

5. AD-HOC WORKING GROUPS

According to specific needs, ICCR Working Groups are established with a precise mandate on an ad-hoc and temporary basis by the members.

Working Groups are created primarily for the purpose of developing proposed guidelines and policy statements that may be adopted by the members.

The Working Group participants are appointed by consensus of the members. Outside technical experts may be invited on an as-needed basis.

Working Group participants appoint their chair and develop a work plan. The Working Groups report regularly to the Regulator's caucus. Work will be completed mainly via teleconference/videoconference or email.

The secretariat functions of Working Groups are ensured by the participant chairing the Working Group.

6. SECRETARIAT

The ICCR Secretariat rotates according to the chairmanship.

The Secretariat:

- provides direct staff support to the chair along the whole meeting;
- assist the chair in preparing the meeting's report and arranges for its distribution to the members at the end of the meeting for its formal adoption;
- maintains a current inventory of all in-process policy documents and ensures that these are shared with members, as required;
- serves as the primary focal point for receipt of all Working Groups that might be created on a temporary basis and other documents for dissemination;
- · makes arrangements for the hand over to the next Secretariat;
- · supports ICCR process at the discretion of the chair.

7. Costs

Members' representatives are responsible for their travel to and from the meeting site and their accommodation.

Industry and other stakeholder representatives are responsible for their own travel and accommodation.

Industry associations may share costs related to the infrastructure (e.g. conference rooms, I.T. facilities) of ICCR meetings.

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